

Application No.: 10/607,571

Reply to Office action of September 9, 2005

Amendments to the Claims:

Please cancel Claim 145.

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claim Listing:

1.-139. Canceled

140. (Currently Amended) A method for treating a patient in need of epinephrine, the method comprising:

administering an effective amount of spray-dried particles to the respiratory system of the patient, the particles comprising:

- (a) epinephrine, or a salt thereof; and
- (b) at least one pharmaceutically acceptable excipient;

wherein the effective amount of particles have a tap density of less than 0.4 g/cm³ and possess a fine particle fraction of less than 5.6 microns of at least about 45 percent.

141. (Previously Presented) The method of Claim 140, wherein the epinephrine, or salt thereof, is present in the particles in an amount ranging from about 1 to about 95 weight percent.

142. (Previously Presented) The method of Claim 141, wherein the epinephrine, or salt thereof, is present in the particles in an amount ranging from about 1 to about 45 weight percent.

143. (Previously Presented) The method of Claim 142, wherein the epinephrine, or salt thereof, is present in the particles in an amount ranging from about 1 to about 30 weight percent.

144. (Previously Presented) The method of Claim 140, wherein the particles are aerodynamically light.

145. Canceled

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146. (Currently Amended) The method of Claim 140, wherein the particles are ~~is substantially~~ amorphous.
147. (Currently Amended) The method of Claim 140, wherein the epinephrine, or salt thereof, contained in the particles is ~~substantially~~ amorphous.
148. (Currently Amended) The method of Claim 140, wherein the epinephrine, or salt thereof, contained in the particles is ~~substantially~~ crystalline.
149. (Currently Amended) The method of Claim 140, wherein the pharmaceutically acceptable excipient contained in the particles is ~~substantially~~ amorphous.
150. (Currently Amended) The method of Claim 140, wherein the pharmaceutically acceptable excipient contained in the particles is ~~substantially~~ crystalline.
151. (Previously Presented) The method of Claim 140, wherein the particles are administered via inhalation.
152. (Previously Presented) The method of Claim 151, wherein the particles comprise at least about 50 micrograms of epinephrine and are administered in a single inhalation.
153. (Previously Presented) The method of Claim 152, wherein the particles comprise about 250 micrograms to about 5 milligrams of epinephrine and are administered in a single inhalation.
154. (Previously Presented) The method of Claim 140, wherein the particles are administered to the respiratory system via a breath activated inhaler.
155. (Previously Presented) The method of Claim 154, wherein the particles are administered to the respiratory system in a single breath activated step.

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156. (Previously Presented) The method of Claim 140, wherein a first portion of the particles is deposited in the airways of the respiratory system and a second portion of the particles is deposited to the alveoli region of the lungs.
157. (Previously Presented) The method of Claim 140, wherein administering an effective amount of particles includes delivering a portion of the particles to the alveoli region of the lungs.
158. (Previously Presented) The method of Claim 140, wherein administering an effective amount of particles includes delivering a portion of the particles to the upper airways.
159. (Previously Presented) The method of Claim 140, wherein the epinephrine is released from the particles and acts systemically.
160. (Previously Presented) The method of Claim 140, wherein the epinephrine is released from the particles and acts locally.
161. (Previously Presented) The method of Claim 140, wherein the patient in need of epinephrine is suffering from anaphylaxis.
162. (Previously Presented) The method of Claim 140, wherein the patient in need of epinephrine exhibits at least one of the conditions selected from the group consisting of bronchoconstriction, bronchospasm, airway constriction, and edema.
163. (Previously Presented) The method of Claim 140, wherein the coefficient of variation for the maximum epinephrine concentration, C_{MAX} , in the patient's blood plasma of a dose of epinephrine is lower than for a non-intravenous injection of the same dose of epinephrine.

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164. (Previously Presented) The method of Claim 163, wherein the non-intravenous injection is selected from the group consisting of a subcutaneous injection, an intramuscular injection, and an auto-injection.
165. (Previously Presented) The method of Claim 140, wherein the coefficient of variation for the time for maximum epinephrine concentration, T_{MAX} , in the patient's blood plasma of a dose of epinephrine is lower than for a non-intravenous injection of the same dose of epinephrine.
166. (Previously Presented) The method of Claim 165, wherein the non-intravenous injection is selected from the group consisting of a subcutaneous injection, an intramuscular injection, and an auto-injection.
167. (Previously Presented) The method of Claim 140, wherein the average time for maximum epinephrine concentration, T_{MAX} , in the patient's blood plasma of a dose of epinephrine is lower than for a non-intravenous injection of the same dose of epinephrine.
168. (Previously Presented) The method of Claim 165, wherein the non-intravenous injection is selected from the group consisting of a subcutaneous injection, an intramuscular injection, and an auto-injection.
169. (Previously Presented) The method of Claim 140, wherein the median time to maximum epinephrine concentration, T_{MAX} , in the patient's blood plasma is less than about 5 minutes.
170. (Previously Presented) The method of Claim 140, wherein the resulting epinephrine C_{MAX} in the patient's blood plasma is about 2 to about 3 times greater than epinephrine C_{MAX} in the patient's blood plasma provided by administration of a liquid-based aerosol.

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171. (Previously Presented) The method of Claim 140, wherein the epinephrine is released from the particles in a sustained manner.
172. (Previously Presented) Particles for delivery of epinephrine to the respiratory system, the particles comprising:
- (a) about 11 to about 21 weight percent epinephrine bitartrate;
 - (b) about 62 to about 82 weight percent leucine; and
 - (c) about 7 to about 17 weight percent sodium tartrate.
173. (Previously Presented) A method for treating a patient in need of epinephrine, the method comprising:
- administering an effective amount of particles to the respiratory system of a patient, the particles comprising:
- (a) about 11 to about 21 weight percent epinephrine bitartrate;
 - (b) about 62 to about 82 weight percent leucine; and
 - (c) about 7 to about 17 weight percent sodium tartrate.